In the United States Patent and Trademark Office
Before the Board of Patent Appeals and Interferences

Appl. No.	:	10/544,151	Confirmation No. 6429
Applicant	:	Francis X. Smith	
Filed	:	August 1, 2005	Art Unit: 1612
Title	:	OPHTHALMIC AND CONTACT LENS SOLUTIONS CONTAINING SIMPLE SACCHARIDES AS PRESERVATIVE ENHANCERS	
Examiner	:	Zohreh A. Fay	
Docket No.	:	3009108 US01	
Customer No.	:	44,331	

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APPEAL BRIEF FOR APPLICANT PURSUANT TO 37 C.F.R. 41.37 AND 35 U.S.C. 134

Sir:

Appellants hereby appeal to the Board of Patent Appeals and Interferences from the Examiner's Final Rejection of claims 1-4 and 6-11 which was contained in the Office Action mailed June 29, 2010 and the Advisory Action mailed December 13, 2010.

A timely Notice of Appeal in compliance with 37 CFR 41.31 is filed herewith.

I. Table of Contents

APPELLANT'S BRIEF ON APPEAL

II. Real Party In Interest

The real party in interest is the assignee of the application, FXS Ventures, LLC, having a place of business in the city of Salem, New Hampshire.

III. Related Appeals and Interferences

No appeals or interferences are known which will directly affect or be directly affected by or have bearing on the Board's decision in the pending appeal.

IV. Status of the Claims

Claims 1-4 and 6-11 are pending in the application.

Claim 5 is cancelled.

Claims 1-4 and 6-11 are rejected.

Claims 1-4 and 6-11 are hereby appealed.

Appendix I provides a clean, double spaced copy of the claims on appeal.

V. Status of Amendments

A response after Final, including only remarks, was filed on November 29, 2010, subsequent to the Final Rejection. An Advisory Action dated December 13, 2010 was then received indicating that the Examiner considered, but did not find that the remarks were sufficiently persuasive to place the Application in condition for allowance.

VI. Summary of Claimed Subject Matter

The invention relates to a single-part ophthalmic solution, a single-part contact lens solution and a method for providing a single-part ophthalmic, the solution containing 0.001 to 10 weight percent of a simple saccharide (in particular embodiments the simple

saccharide being inositol, mannitol, sorbitol, sucrose, dextrose, or glycerin) and at least 0.0001 weight to 10 weight percent polyhexamethylene biguanide, the solution being physiologically compatible with direct contact with corneal tissue and having improved preservative efficacy.

Independent claim 1 recites a contact lens solution (Para. [0005]) comprising 0.001 to 10 weight percent of a preservative enhancer (Para. [0006]) chosen from the group consisting of: inositol (Para. [0006]); mannitol (Para. [0006]); sorbitol (Para. [0006]); sucrose (Para. [0006]); dextrose (Para. [0006]); and glycerin (Para. [0006]); at least 0.0001 weight percent of polyhexamethylene biguanide (Para. [0007]); and where the concentration of chloride in said solution is less than 0.2 percent by weight (Para. [0006]); wherein said solution is an aqueous solution effective as a single-part solution (Para. [0029]); wherein said solution is physiologically compatible with direct contact with corneal tissue (Para. [0003]).

Independent claim 8 recites an ophthalmic solution (Para. [0005]) comprising 0.001 to 10 weight percent sorbitol (Para. [0006]), at least 0.0001 weight percent polyhexamethylene biguanide (Para. [0007]), and less than 0.2 weight percent chloride (Para. [0006]); wherein said solution is an aqueous solution effective as a single-part solution (Para. [0029]); wherein said solution is physiologically compatible with direct contact with corneal tissue (Para. [0003]).

Independent claim 9 recites a contact lens solution (Para. [0005]) comprising as a preservative enhancer 0.001 to 10 weight percent of a simple saccharide (Para. [0006]); and at least 0.0001 weight to 10 weight percent polyhexamethylene biguanide (Para. [0007]); wherein said solution is an aqueous solution effective as a single-part solution (Para. [0029]); wherein said solution is physiologically compatible with direct contact with corneal tissue (Para. [0003]).

Independent claim 11 recites a method for providing an ophthalmic solution (Para. [0005]) comprising: contacting an eye (Para. [0003]) with a single-part solution (Para. [0029]) comprising 0.001 to 10 weight percent of a preservative enhancer (Para. [0006]) chosen from the group consisting of: inositol (Para. [0006]); mannitol (Para. [0006]); sorbitol (Para. [0006]); sucrose (Para. [0006]); dextrose (Para. [0006]); and glycerin (Para. [0006]); at least 0.0001 weight percent of polyhexamethylene biguanide

(Para. [0007]); and where the concentration of chloride in said solution is less than 0.2 percent by weight (Para. [0006]).

VII. Grounds of Rejection to be Reviewed on Appeal

The following issue is presented for review by the Board of Patent Appeals and Interferences:

1. Whether claims 1-4, 6-7 and 9-10 are unpatentable under 35 § U.S.C. 103(a) over Asgharian et al. (U.S. Patent No. 6,139,646).

2. Whether claim 8 is unpatentable under 35 § U.S.C. 103(a) over Asgharian et al. (U.S. Patent No. 6,139,646).

3. Whether claim 11 is unpatentable under 35 § U.S.C. 103(a) over Asgharian et al. (U.S. Patent No. 6,139,646).

VIII. Arguments

Rejection of Claims 1-4, 6-7 and 10 under 35 U.S.C. § 103(a):

The Office Action dated June 29, 2010 rejects claims 1-4 and 6-11 under 35 U.S.C. § 103(a) as being unpatentable over Asgharian et al. (U.S. 6,139,646) indicating that Asgharian et al. teaches the use of a simple saccharide in a composition that contains PHMB. In light of the following remarks and the previously submitted declaration of Mr. Ed Jahngen, it is respectfully requested that this rejection be reversed.

Claims 1-4, 6-7 and 10 relate to a contact lens solution which is physiologically compatible with direct contact with corneal eye tissue. When utilizing a contact lens solution that comes in direct contact with the eye, it is important to ensure that none of the components of the solution would provide any adverse effects. When determining the patentability of the claims, the invention must be viewed as whole. "[A] patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the 'subject matter as a whole' which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103." *In re Sponnoble*, 405 F.2d 578, 585 (CCPA 1969).

Enzyme solutions, such as those taught by Asgharian et al., are often used to digest protein build up on contact lenses. The enzymes digest the protein and therefore remove the build up on the lens. However, enzyme solutions are detrimental to corneal tissue when they come in direct contact with the eye. The enzyme solution digests the proteins naturally found in the eye causing severe adverse effects. Therefore, it is important to properly rinse and then disinfect contact lenses after using an enzyme solution prior to returning the contact lens to the eye.

In the Final Rejection dated June 29, 2010, the examiner has indicated that the arguments and declaration have been considered, but are not deemed to be persuasive. When an applicant submits evidence, in reply to a rejection, the examiner must reconsider the patentability of the claimed invention. The decision on patentability must be made based upon consideration of all the evidence. A decision to make or maintain a rejection in the face of all the evidence must show that it was based on the totality of the evidence. Facts established by rebuttal evidence must be evaluated along with the facts on which the conclusion of obviousness was reached, not against the conclusion itself. *In re Eli Lilly & Co.*, 902 F.2d 943 (Fed. Cir. 1990). To properly evaluate the evidence, the reference itself must be evaluated.

In reviewing a reference, it is required that the reference be viewed as a whole. The totality of the prior art must be considered, and proceeding contrary to accepted wisdom in the art is evidence of nonobviousness. *In re Hedges,* 783 F.2d 1038 (Fed. Cir. 1986). Asgharian et al. relates, as a whole, to an enzyme solution. This is evidenced by the claims, examples, specification and abstract. Each claim recites a solution containing alkyl trypsin to produce an enzyme solution. Furthermore, the examples all relate to forming either a multi-purpose composition, or a two-part composition, both containing an enzyme for the digestion of proteins. Even the abstract discloses that the reference is directed to a liquid enzyme composition for cleaning a contact lens. When reading Asgharian et al. as a whole, the reference is directed towards enzyme solutions.

Reading Asgharian et al. as a whole, the teachings are related to a liquid enzyme composition (abstract) for cleaning a contact lens. However, this enzyme composition would not be suitable for direct eye contact as enzyme solutions are known to those skilled in the art to be harmful to the eye. Applicant kindly direct attention to Exhibit 1

first submitted with the response filed April 12, 2010 (a courtesy copy is submitted along with this request), the declaration of Mr. Ed Jahngen, filed under 37 C.F.R. §132 ("Declaration"), indicating that enzyme solutions, such as those disclosed by Asgharian et al. are not suitable for in-eye applications. Declaration, Para. 9. The Declaration indicates that enzyme solutions are used to digest protein build up on contact lenses, and if the enzyme solution were to come in direct contact with the eye, the solution would digest the proteins naturally found in the eye thereby causing adverse effects. Declaration, Paras 5 – 6. A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983). Here, when viewing the reference as a whole, the reference leads away from the claimed invention.

Regarding the indication in the Advisory Action dated December 13, 2010 that Asgharian et al. teaches a solution that is suitable for direct contact with corneal tissue, Col. 9, Lns. 61 – 63 of Asgharian et al. explicitly indicates that the multi-purpose composition is intended to function as storing, rinsing, cleaning and disinfecting solutions. None of these solutions are used for direct contact with corneal tissue, and as discussed above, must be rinsed away prior to placing a contact lens in an eye to avoid corneal damage. Asgharian et al. is silent regarding direct contact with corneal tissue. Because of the dangers of enzyme solutions, it is imperative to rinse any remaining enzyme solution away from a contact lens prior to placing the lens in contact with an eye. Declaration, Para. 7. Although enzyme solutions, such as those disclosed by Asgharian et al., may be physiologically compatible as storing, rinsing, cleaning and disinfecting solutions, enzyme solutions are not suitable for direct contact with corneal tissue as claimed. It is understood that even in the applied functions of storing, rinsing, cleaning and disinfecting, such enzyme solutions would be rinsed away prior to placing a contact lens in contact with an eye to prevent the enzyme from digesting the healthy proteins naturally found in the eye.

It is well established that "[k]nown disadvantages in old devices which would naturally discourage search for new inventions may be taken into account in determining obviousness." *United States v. Adams,* 383 U.S. 39, 52 (1966). Based on the evidence previously submitted, it is clear that enzyme solutions are not suitable for direct contact

with the eye. In viewing Asgharian et al. as a whole, the reference is directed to enzyme based solutions.

As the instant claims recite a contact lens solution that is physiologically compatible with direct contact with corneal tissue, and, as evidenced by the Declaration, enzyme solutions are not suitable for in-eye applications, it is respectfully requested that this rejection be reversed.

Rejection of Claim 8 under 35 U.S.C. § 103(a):

As discussed above, the Office Action dated June 29, 2010 rejects claims 1-4 and 6-11 under 35 U.S.C. § 103(a) as being unpatentable over Asgharian et al. (U.S. 6,139,646) indicating that Asgharian et al. teaches the use of a simple saccharide in a composition that contains PHMB. In addition to the above remarks regarding claims 1-4, 6-7 and 9-10, the Declaration of Mr. Ed Jahngen, and the following remarks, it is respectfully requested that this rejection be reversed.

Claim 8 relates to an ophthalmic solution which is physiologically compatible with direct contact with corneal eye tissue. As discussed above, Asgharian et al. does not disclose a solution that is suitable for direct contact with corneal eye tissue. Also as discussed above, Col. 9, Lns. 61 – 63 of Asgharian et al. explicitly indicates that the multi-purpose composition is intended to function as storing, rinsing, cleaning and disinfecting solutions. These solutions must be rinsed away prior to contact with corneal tissue to avoid eye damage.

As the instant claims recite an ophthalmic solution that is physiologically compatible with direct contact with corneal tissue, and, as evidenced by the Declaration, enzyme solutions are not suitable for in-eye applications, it is respectfully requested that this rejection be reversed.

Rejection of Claim 11 under 35 U.S.C. § 103(a):

As discussed above, the Office Action dated June 29, 2010 rejects claims 1-4 and 6-11 under 35 U.S.C. § 103(a) as being unpatentable over Asgharian et al. (U.S.

6,139,646) indicating that Asgharian et al. teaches the use of a simple saccharide in a composition that contains PHMB. In addition to the above remarks regarding claims 1-4, 6-7 and 9-10, the Declaration of Mr. Ed Jahngen, and the following remarks, it is respectfully requested that this rejection be reversed.

Claim 11 relates to a method for providing an ophthalmic solution having the step of contacting an eye with a single-part solution. As discussed above, Asgharian et al. does not disclose a solution that is suitable for direct contact with an eye. Furthermore, Asgharian et al. is silent regarding a method for providing an ophthalmic solution that involves the step of contacting an eye with a single-part solution. As discussed above, Col. 9, Lns. 61 – 63 of Asgharian et al. explicitly indicates that the multi-purpose composition is intended to function as storing, rinsing, cleaning and disinfecting solutions. None of these solutions are used for direct contact with the eye. Therefore, it is respectfully requested that this rejection be reversed.

IX. Summary

Asgharian et al. does not teach or disclose a solution that is suitable for direct contact with corneal eye tissue. Instead, Asgharian et al. teaches the use of an enzyme solution. Enzyme solutions are known to digest proteins, including those proteins found naturally in the eye. Due to the dangers of placing enzyme solutions, even when cleaning a contact lens with an enzyme solution, it is required to first rinse away the solution prior to placing the contact in the eye. As such, enzyme solutions are not suitable for direct contact with corneal eye tissue. Therefore, it is respectfully urged that the rejection be reversed.

X. Conclusion

For the above reasons, Appellants respectfully request that the Board of Patent Appeals and Interferences reverses the rejection by the Examiner and mandate the allowance of claims 1-4 and 6-11.

Respectfully submitted,

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XI. Appendix I - Claims on Appeal

1. A contact lens solution comprising 0.001 to 10 weight percent of a preservative enhancer chosen from the group consisting of: inositol; mannitol; sorbitol; sucrose; dextrose; and glycerin; at least 0.0001 weight percent of polyhexamethylene biguanide; and where the concentration of chloride in said solution is less than 0.2 percent by weight; wherein said solution is an aqueous solution effective as a single-part solution;

wherein said solution is physiologically compatible with direct contact with corneal tissue.

2. The contact lens solution of claim 1, wherein the concentration of said polyhexamethylene biguanide is between 1 and 100 parts per million.

3. The contact lens solution of claim 1, further comprising a physiologically compatible buffer selected from the group consisting of phosphate, bicarbonate, citrate, borate, ACES, BES, BICINE, BIS-Tris, BIS-Tris Propane, HEPES, TRIS, HEPPS, imidazole, MES, MOPS, PIPES, TAPS, TES, and Tricine.

4. The contact lens solution of claim 1, further comprising between 0.01 % and 5.0% glycerin.

5. (Cancelled).

6. The contact lens solution of claim 1 further comprising a wetting agent selected from the group consisting of polysorbate surfactants, polyoxyethylene surfactants, phosphonates, saponins and polyethoxylated castor oils.

7. The contact lens solution of claim 1 further comprising a sequestering agent selected from the group consisting as ethylenediaminetetraacetic acid, phosphonates, citrate, gluconate and tartarate.

8. An ophthalmic solution comprising 0.001 to 10 weight percent sorbitol, at least 0.0001 weight percent polyhexamethylene biguanide, and less than 0.2 weight percent chloride; wherein said solution is an aqueous solution effective as a single-part solution;

wherein said solution is physiologically compatible with direct contact with corneal tissue.

9. A contact lens solution comprising as a preservative enhancer 0.001 to 10 weight percent of a simple saccharide; and at least 0.0001 weight to 10 weight percent polyhexamethylene biguanide; wherein said solution is an aqueous solution effective as a single-part solution;

wherein said solution is physiologically compatible with direct contact with corneal tissue.

10. The contact lens solution of claim 3, wherein said physiologically compatible buffer is selected from the group consisting of phosphate, bicarbonate, citrate,

ACES, BES, BICINE, BIS-Tris, BIS-Tris Propane, HEPES, HEPPS, imidazole, MES, MOPS, PIPES, TAPS, TES, and Tricine.

11. A method for providing an ophthalmic solution comprising:

contacting an eye with a single-part solution comprising 0.001 to 10 weight percent of a preservative enhancer chosen from the group consisting of: inositol; mannitol; sorbitol; sucrose; dextrose; and glycerin; at least 0.0001 weight percent of polyhexamethylene biguanide; and where the concentration of chloride in said solution is less than 0.2 percent by weight.

XII. Appendix II - Evidence

Declaration of Mr. Ed Jahngen, filed under 37 C.F.R. 132 and first submitted with the response dated April 12, 2010.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/544,151	Confirmation No. 6429
Applicant	:	Francis X. Smith	
Filed	:	August 1, 2005	Art Unit: 1612
Title	:	OPHTHALMIC AND CONTACT LENS SOLUTIONS CONTAINING SIMPLE SACCHARIDES AS PRESERVATIVE ENHANCERS	
Examiner	:	Zohreh A. Fay	
Docket No.	:	3009108 US01	
Customer No.	:	44,331	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA. 22313-1450

Sir:

DECLARATION UNDER 37 C.F.R. §132

I, Ed Jahngen, do hereby declare and say:

1. I, Ed Jahngen, am a resident of Kingston, in Rochester County in the State of New Hampshire. I am a citizen of the USA. I received a Bachelor of Science degree in Chemistry in 1968 from Bates College. I received a PhD in Chemistry from the University of Vermont in 1974. I have been employed by University of Massachusetts since 1982 and engaged since that time in the field of ophthalmic application among other biochemical pursuits. I am a named inventor or co-inventor on over 10 issued United States Patents related to my research and development activities. For these reasons I consider myself an expert in the field of ophthalmic applications.
2. I am familiar with the Office Action, and the references cited herein.
3. The above-referenced pending application is directed to an ophthalmic solution, and more specifically in one embodiment a contact lens solution, and a method for applying the

solution containing a select group of simple saccharides; a preservative, and not more than about 0.2 percent by weight chloride. The solution being an aqueous solution effective as a single-part solution and is physiologically compatible with direct contact with corneal tissue.

4. The applied reference of Asgharian et al. is directed to a liquid enzyme composition for cleaning a contact lens.
5. Enzyme solutions, such as those taught by Asgharian et al., are often used to digest protein build up on contact lenses.
6. Enzyme solutions are harmful when they come in direct contact with the eye. The enzymes are capable of digesting the proteins naturally found in the eye causing severe adverse effects.
7. When using enzyme solutions it is imperative to rinse away the enzyme solution prior to placing the contact lens in the eye.
8. The claims of the instant application require that the solution be physiologically acceptable for direct contact with corneal tissue.
9. Do to the extreme dangers of enzyme solutions, such as those disclosed by Asgharian et al., it is not suitable to use an enzyme solution for in-eye applications.
10. I further declare that all statements made herein are of my own knowledge are true and all statements made on information and belief are believed to be true. These statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 29. March. 2010

Ed Jahngen

Appendix III – Related Proceedings

None